

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD.,)	
Plaintiff,)	
v.)	
SAREPTA THERAPEUTICS, INC.,)	
)	
Defendant.)	C.A. No. 21-1015-GBW
)	
SAREPTA THERAPEUTICS, INC.,)	JURY TRIAL DEMANDED
Defendant and Counter-Plaintiff,)	
v.)	
NIPPON SHINYAKU CO., LTD. and)	
NS PHARMA, INC.)	
)	
Plaintiff and Counter-Defendants.)	
)	

[PROPOSED] SCHEDULING ORDER [PATENT, NON-ANDA]

This 12th day of December, 2022, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS HEREBY ORDERED that:

1. Rule 26(a)(1) Initial Disclosures and E-Discovery Default Standard. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) within five (5) days of the date the Court enters this Order. If they have not already done so, the parties are to review the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("ESI"), which is posted at <http://www.ded.uscourts.gov> (*see* Other Resources, Default Standard for Discovery) and is incorporated herein by reference.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before **March 23, 2023**.

Unless otherwise ordered by the Court, any motion to join a party or motion to amend the pleadings shall be made pursuant to the procedures set forth in Paragraphs 4(g) and 5.

3. Disclosures. Absent agreement among the parties, and approval of the Court:

(a) **By April 18, 2022**, Plaintiff and Counterclaim-Plaintiff shall identify the accused product(s), including accused methods and systems, and its damages model, as well as the asserted patent(s) that the accused product(s) allegedly infringe(s). Plaintiff and Counterclaim-Plaintiff shall also produce the file history for each asserted patent.

(b) **By May 18, 2022**, Defendant and Counterclaim-Defendants shall produce core technical documents related to the accused product(s), sufficient to show how the accused product(s) work(s), including but not limited to non-publicly available operation manuals, product literature, schematics, and specifications. Defendant and Counterclaim-Defendants shall also produce sales figures for the accused product(s).

(c) **By June 17, 2022**, Plaintiff and Counterclaim-Plaintiff shall produce an initial claim chart relating each known accused product to the asserted claims each such product allegedly infringes.

(d) **By July 18, 2022**, Defendant and Counterclaim-Defendants shall produce its initial invalidity contentions for each asserted claim, as well as the known related invalidating references.

(e) **By June 22, 2023**, Defendant and Counterclaim-Plaintiff shall provide final infringement contentions.

(f) By **July 11, 2023**, Defendant and Counterclaim-Defendants shall provide final invalidity contentions.

(g) By **July 11, 2023**, Defendant and Counterclaim-Defendants shall provide final non-infringement contentions.

(h) By **July 20, 2023**, Plaintiff and Counterclaim-Plaintiff shall provide final validity contentions.

4. Discovery. Unless otherwise ordered by the Court or agreed to by parties, the limitations on discovery set forth in the Federal Rules of Civil Procedure shall be strictly observed.

(a) Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before **July 27, 2023**.

(b) Document Production. Document production shall be substantially complete by **January 20, 2023**.

(c) Requests for Admission. A maximum of **60** requests for admission are permitted for each side. Requests for admission that are limited only to authentication of documents shall not be counted against this limit.

(d) Interrogatories.

i. A maximum of **35** interrogatories, including contention interrogatories, are permitted for each side.

ii. The Court encourages the parties to serve and respond to contention interrogatories early in the case. In the absence of agreement among the parties, contention interrogatories, if filed, shall first be addressed by the party with the burden of proof.

The adequacy of all interrogatory answers shall be judged by the level of detail each party provides (*i.e.*, the more detail a party provides, the more detail a party shall receive).

(e) Depositions.

i. Limitation on Hours for Deposition Discovery. Each side is limited to a total of **100** hours of taking testimony by deposition upon oral examination. For any witness who testifies in a foreign language with an interpreter, each two hours of deposition testimony shall be counted as **one hour and 15 minutes**.

ii. Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this district court must ordinarily be required, upon request, to submit to a deposition at a place designated within this district. Exceptions to this general rule may be made by order of the Court. A defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision. The parties will meet and confer about any restrictions on location and procedures for depositions in view of the COVID-19 pandemic and travel conditions.

(f) Disclosure of Expert Testimony.

i. Expert Reports. For the party who has the initial burden of proof on the subject matter, the initial Federal Rule of Civil Procedure 26(a)(2) disclosure of expert testimony is due on or before **August 14, 2023**. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before **September 11, 2023**. Reply expert reports from the party with the initial burden of proof are due on or before **October 2, 2023**. No other expert reports will be permitted without either the consent of all

parties or leave of the Court. Along with the submissions of the expert reports, the parties shall advise of the dates and times of their experts' availability for deposition.

ii. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than the deadline for dispositive motions set forth herein, unless otherwise ordered by the Court. Briefing on such motions is subject to the page limits set out in connection with briefing of case dispositive motions.

iii. Expert Discovery Cut-Off. All expert discovery in this case shall be initiated so that it will be completed on or before **October 30, 2023.**

(g) Discovery Matters and Disputes Relating to Protective Orders.

i. Any discovery motion filed without first complying with the following procedures will be denied without prejudice to renew pursuant to these procedures.

ii. Should counsel find, after good faith efforts - including verbal communications among Delaware and Lead Counsel for all parties to the dispute - that they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall submit a joint letter in substantially the following form:

Dear Judge Williams:

The parties in the above-referenced matter write to request the scheduling of a discovery teleconference.

The following attorneys, including at least one Delaware Counsel and at least one Lead Counsel per party, participated in a verbal meet-and-confer (in person and/or by telephone) on the following date(s): _____

Delaware Counsel: _____

Lead Counsel: _____

The disputes requiring judicial attention are listed below:

[provide here a non-argumentative list of disputes requiring judicial attention]

iii. On a date to be set by separate order, generally not less than forty-eight (48) hours prior to the conference, the party seeking relief shall file with the Court a letter, not to exceed three (3) pages, outlining the issues in dispute and its position on those issues. On a date to be set by separate order, but generally not less than twenty-four (24) hours prior to the conference, any party opposing the application for relief may file a letter, not to exceed three (3) pages, outlining that party's reasons for its opposition.

iv. Each party shall submit two (2) courtesy copies of its discovery letter and any attachments.

v. Should the Court find further briefing necessary upon conclusion of the telephone conference, the Court will order it. Alternatively, the Court may choose to resolve the dispute prior to the telephone conference and will, in that event, cancel the conference.

5. Motions to Amend.

(a) Any motion to amend (including a motion for leave to amend) a pleading shall **NOT** be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the proposed amended pleading as well as a "blackline" comparison to the prior pleading.

(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to amend.

6. Motions to Strike.

(a) Any motion to strike any pleading or other document shall *NOT* be accompanied by an opening brief but shall, instead, be accompanied by a letter, not to exceed three (3) pages, describing the basis for the requested relief, and shall attach the document to be stricken.

(b) Within seven (7) days after the filing of a motion in compliance with this Order, any party opposing such a motion shall file a responsive letter, not to exceed five (5) pages.

(c) Within three (3) days thereafter, the moving party may file a reply letter, not to exceed two (2) pages, and, by this same date, the parties shall file a letter requesting a teleconference to address the motion to strike.

7. Technology Tutorials. By **January 17, 2023**, the parties jointly shall provide the Court, a tutorial on the technology at issue. In that regard, the parties shall jointly submit to the Court an electronic tutorial of not more than thirty (30) minutes. The tutorial should focus on the technology in issue and educate the Court about the same and should not be used for argument. As to the format selected, the parties should confirm the Court's technical abilities to access the

information contained in the tutorial (“mpeg”, “quicktime”, etc.). The parties may choose to file their tutorial under seal, subject to any protective order in effect.

8. Claim Construction Issue Identification. On or before **October 26, 2022**, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction of those term(s)/phrase(s). On or before **November 22, 2022**, the parties shall respond to and provide their proposed construction for any term(s)/phrase(s) presented by the other side for which the party did not initially provide a construction. These documents will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than **December 15, 2022**. The Joint Claim Construction Chart, in Word format, shall be e-mailed simultaneously with filing to gbw_civil@ded.uscourts.gov. The parties’ Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue, and should include each party’s proposed construction of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A copy of the patent(s) in issue as well as those portions of the intrinsic record relied upon shall be submitted with this Joint Claim Construction Chart. In this joint submission, the parties shall not provide argument.

9. Claim Construction Briefing. Plaintiff and Counterclaim-Plaintiff shall serve, but not file, their opening brief, not to exceed 5,000 words, on **January 5, 2023**. Defendant and Counterclaim-Defendants shall serve, but not file, their answering brief not to exceed 7,500 words, on **February 6, 2023**. Plaintiff and Counterclaim-Plaintiff shall serve, but not file, their reply brief, not to exceed 5,000 words, on **February 27, 2023**. Defendant and Counterclaim-Defendants shall serve, but not file their sur-reply brief, not to exceed 2,500 words, on **March**

13, 2023. No later than **March 20, 2023**, the parties shall file a Joint Claim Construction Brief.

The parties shall copy and paste their unfiled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

I. Agreed-Upon Constructions

II. Disputed Constructions

[TERM 1]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

[TERM 2]

1. Plaintiff's Opening Position
2. Defendant's Answering Position
3. Plaintiff's Reply Position
4. Defendant's Sur-Reply Position

If there are any materials that would be submitted in an index, the parties shall submit them in a Joint Appendix.

The parties may file separate joint claim construction briefs for terms applicable to the patents asserted by Plaintiff and by Counterclaim-Plaintiff. However, the parties shall meet and confer to ensure that the parties request that the Court construe no more than twelve (12) terms across the two joint claim construction briefs.

10. Hearing on Claim Construction. Beginning at **10 a.m. on April 19, 2023**, the Court will hear argument on claim construction. The parties shall notify the Court, by joint letter submission, no later than the date on which their answering claim construction briefs are due: (i) whether they request leave to present testimony at the hearing; and (ii) the amount of time they are requesting be allocated to them for the hearing.

Provided that the parties comply with all portions of this Scheduling Order, and any other orders of the Court, the parties should anticipate that the Court will issue its claim construction order within sixty (60) days of the conclusion of the claim construction hearing. If the Court is unable to meet this goal, it will advise the parties no later than sixty (60) days after the conclusion of the claim construction hearing.

11. Interim Status Report. On **February 23, 2023**, counsel shall submit a joint letter to the Court with an interim report of the matters in issue and the progress of discovery to date. Thereafter, if the Court deems it necessary, it will schedule a status conference.

12. Supplementation. Absent agreement among the parties, and approval of the Court,

- (a) no later than **June 22, 2023** the Plaintiff and Counterclaim-Plaintiff must finally supplement the identification of all accused products and serve final infringement contentions; and
- (b) no later than **July 11, 2023** the accused infringers must finally supplement the identification of all invalidity references and serve final invalidity contentions.

13. Case Dispositive Motions.

(a) All case dispositive motions, an opening brief, and affidavits, if any, in support of the motion shall be served and filed on or before **November 20, 2023**. Answering case dispositive motion briefs shall be filed on or before **December 15, 2023**. Reply case dispositive motion briefs shall be filed on or before **January 10, 2024**. No case dispositive motion under Rule 56 may be filed more than ten (10) days before the above date for opening dispositive motions and briefs without leave of the Court.

(b) Concise Statement of Facts Requirement. Any motion for summary judgment shall be accompanied by a separate concise statement, not to exceed six (6) pages, which details each material fact which the moving party contends is essential for the Court's resolution of the summary judgment motion (not the entire case) and as to which the moving party contends there is no genuine issue to be tried. Each fact shall be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

Any party opposing the motion shall include with its opposing papers a response to the moving party's concise statement, not to exceed six (6) pages, which admits or disputes the facts set forth in the moving party's concise statement on a paragraph-by-paragraph basis. To the extent a fact is disputed, the basis of the dispute shall be supported by specific citation(s) to the record. Failure to respond to a fact presented in the moving party's concise statement of facts shall indicate that fact is not in dispute for purposes of summary judgment. The party opposing the motion may also include with its opposing papers a separate concise statement, not to exceed four (4) pages, which sets forth material facts as to which the opposing party contends there is a genuine issue to be tried. Each fact asserted by the opposing party shall also be set forth in a separate numbered paragraph and shall be supported by specific citation(s) to the record.

The moving party shall include with its reply papers a response to the opposing party's concise statement of facts, not to exceed four (4) pages, on a paragraph-by-paragraph basis. Failure to respond to a fact presented in the opposing party's concise statement of facts shall indicate that fact remains in dispute for purposes of summary judgment.

(c) Page limits combined with Daubert motion page limits. Each party is permitted to file as many case dispositive motions as desired provided, however, that each **SIDE** will be limited to a combined total of 40 pages for all opening briefs, a combined total of 40 pages for all answering briefs, and a combined total of 20 pages for all reply briefs regardless of the number of case dispositive motions that are filed. In the event that a party files, in addition to a case dispositive motion, a Daubert motion to exclude or preclude all or any portion of an expert's testimony, the total amount of pages permitted for all case dispositive and Daubert motions shall be increased to 50 pages for all opening briefs, 50 pages for all answering briefs, and 25 pages for all reply briefs for each **SIDE**.¹

(d) Ranking of Summary Judgment Motions. Any party that files more than one summary judgment motion shall number each motion to indicate the order in which the party wishes the Court to review its pending motions. The first motion the party wishes the Court to consider shall be designated #1, the second motion shall be designated #2, and so on. The Court will review the party's summary judgment motions in the order designated by the party. If the Court decides to deny a motion filed by the party, barring exceptional reasons determined *sua sponte* by the Court, the Court will not review any lower ranked summary judgment motions filed by the party.

¹ The parties must work together to ensure that the Court receives no more than a total of 250 pages (i.e., 50 + 50 + 25 regarding one side's motions, and 50 + 50 + 25 regarding the other side's motions) of briefing on all case dispositive motions and Daubert motions that are covered by this scheduling order and any other scheduling order entered in any related case that is proceeding on a consolidated or coordinated pretrial schedule.

14. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

15. Application to Court for Protective Order. A Stipulated Protective Order was entered by the Court on June 21, 2022.

16. Papers Filed Under Seal. In accordance with section G of the Revised Administrative Procedures Governing Filing and Service by Electronic Means, a redacted version of any sealed document shall be filed electronically within seven (7) days of the filing of the sealed document.

17. Courtesy Copies. The parties shall provide to the Court two (2) courtesy copies of filings (*i.e.*, briefs, appendices, exhibits, declarations, affidavits etc.). Courtesy copies of appendices and exhibits should include hard tabs. This provision also applies to papers filed under seal.

18. Motions in Limine. Motions in *limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each **SIDE** shall be limited to three (3) *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three (3) pages of argument, may be opposed by a maximum of three (3) pages of argument, and the side making the *in limine* request may add a maximum of one (1) additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three (3) page submission (and, if the moving party, a single one (1) page reply), unless otherwise ordered

by the Court. No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

19. Pretrial Conference. On May 6, 2024, the Court will hold a pretrial conference in Court with counsel beginning at 4:30 p.m. Unless otherwise ordered by the Court, the parties should assume that filing the pretrial order satisfies the pretrial disclosure requirement of Federal Rule of Civil Procedure 26(a)(3). The parties shall file with the Court the joint proposed final pretrial order in compliance with Local Rule 16.3(c) and the Court's Preferences and Procedures for Civil Cases not later than seven (7) days before the pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d)(1)-(3) for the preparation of the joint proposed final pretrial order.

The parties shall provide the Court two (2) courtesy copies of the joint proposed final pretrial order and all attachments. The proposed final pretrial order shall contain a table of contents and the paragraphs shall be numbered.

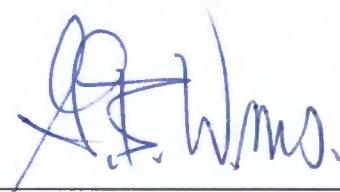
20. Jury Instructions, Voir Dire, and Special Verdict Forms. Where a case is to be tried to a jury, pursuant to Local Rules 47.1(a)(2) and 51.1 the parties should file (i) proposed voir dire, (ii) preliminary jury instructions, (iii) final jury instructions, and (iv) special verdict forms seven (7) business days before the final pretrial conference. This submission shall be accompanied by a courtesy copy containing electronic files of these documents, in Microsoft Word format, which may be submitted by e-mail to gbw_civil@ded.uscourts.gov.

21. Trial. This matter is scheduled for a **seven (7)** day jury trial beginning at 9:30 a.m. on **May 13, 2024**, with the subsequent trial days beginning at 9:30 a.m. Until the case is submitted to the jury for deliberations, the jury will be excused each day at 5:30 p.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases.

22. Judgment on Verdict and Post-Trial Status Report. Within seven (7) days after a jury returns a verdict in any portion of a jury trial, the parties shall jointly submit a form of order to enter judgment on the verdict. At the same time, the parties shall submit a joint status report, indicating among other things how the case should proceed and listing any post-trial motions each party intends to file.

23. Post-Trial Motions. Unless otherwise ordered by the Court, all **SIDES** are limited to a maximum of 20 pages of opening briefs, 20 pages of answering briefs, and 10 pages of reply briefs relating to any post-trial motions filed by that side, no matter how many such motions are filed.

24. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.



The Honorable Gregory B. Williams
United States District Judge

CHART OF RELEVANT DATES²

EVENT	DEADLINE
Parties shall respond to and provide their proposed construction for any term(s)/phrase(s) presented by the other side for which the party did not initially provide a construction. (¶ 8)	November 22, 2022
Filing of Joint Claim Construction Chart (¶ 9)	December 15, 2022
Plaintiffs' Opening Claim Construction Brief & Counter-Claim Plaintiffs' Opening Claim Construction Brief (¶ 9)	January 5, 2023
Deadline to Submit Joint Technology Tutorial (¶ 7)	January 17, 2023
Substantial Completion of Document Production (¶ 4(b))	January 20, 2023
Defendants' Answering Claim Construction Brief & Counterclaim-Claim Defendants' Answering Claim Construction Brief (¶ 9)	February 6, 2023
Interim Status Report (¶11)	February 23, 2023
Plaintiffs' Reply Claim Construction Brief & Counterclaim-Plaintiffs' Reply Claim Construction Brief (¶ 9)	February 27, 2023

² Dates which have already passed and were set forth in the previous Scheduling Order (D.I. 124) are omitted from the chart.

EVENT	DEADLINE
Defendant's Sur-Reply Claim Construction Brief & Counterclaim-Defendants' Reply Claim Construction Brief (¶ 9)	March 13, 2023
Filing of Joint Claim Construction Briefs (¶ 9)	March 20, 2023
Last Day to Join Other Parties and to Amend the Pleadings (¶ 2)	March 23, 2023
Claim Construction Hearing (¶ 10)	April 19, 2023
Deadline for Plaintiffs & Counterclaim-Plaintiff to Supplement Identification of All Accused Products (¶ 12a)	June 22, 2023
Plaintiffs & Counterclaim Plaintiff to Provide Final Infringement Contentions (¶ 12a)	June 22, 2023
Deadline for Defendants & Counterclaim-Defendants to Supplement Invalidity References (¶ 12b)	July 11, 2023
Defendant & Counterclaim-Defendants to Provide Final Invalidity Contentions (¶ 7f)	July 11, 2023
Defendant & Counterclaim-Defendants to Provide Final Non-Infringement Contentions (¶ 3g)	July 11, 2023
Plaintiff & Counterclaim-Plaintiff to Provide Final Validity Contentions (¶ 7h)	July 20, 2023

EVENT	DEADLINE
Fact Discovery Cut Off (¶ 4a)	July 27, 2023
Opening Expert Reports (¶ 4f)	August 14, 2023
Rebuttal Expert Reports (¶ 4f)	September 11, 2023
Reply Expert Reports (¶ 4f)	October 2, 2023
Close of Expert Discovery (¶ 4f)	October 30, 2023
Case Dispositive Motions (Opening Briefs) (¶13a)	November 20, 2023
Answering Case Dispositive Briefs (¶13a)	December 15, 2023
Reply Case Dispositive Briefs (¶13a)	January 10, 2024
Deadline to File Proposed Voir Dire, Preliminary Jury Instructions, and Final Jury Instructions (¶ 20)	7 days before Pretrial Conference
Deadline to File Joint Proposed Final Pretrial Order (¶ 19)	7 days before Pretrial Conference
Pretrial Conference (¶ 19)	May 6, 2024
Trial (7-day jury) (¶ 21)	May 13, 2024